K090349

MAR - 9 2009

# 510(k) Summary

| | |
|---|---|
| Date prepared | February 10, 2008 |
| 510(k) Owner | Orbital Therapy, LLC<br>8 Alfred Circle<br>Bedford, MA 01730<br><br>Phone: 508-202-7224<br>Fax: 508-371-3434 |
| Contact | Natalya Koshnitsky, Manager, Regulatory Affairs |
| Trade name | ClearVue Prone Breast Treatment Table |
| Common name | Breast radiation therapy patient support |
| Classification Name | Medical charged-particle radiation therapy system |
| Regulation: | 21 CFR 892.5050 |
| Product code: | IYE |
| Predicate device | Bionix RT-6025 Prone Breast System, which was cleared to market in 510(k) # K905007 |
| Device description | ClearVue is a prone-breast table top attachment, which allows for multi-angle access to the treatment anatomy. This device is compatible with mainstream linear accelerators as well as compatible with most existing CT scanners. ClearVue is placed on top of the existing treatment or imaging modality couch. ClearVue does not have motors for mechanical motion. ClearVue is compatible with both left and right breast patients by the use of variable inserts. An optional support cushion is used should one find it necessary to tilt the patient. ClearVue passes through a standard CT opening with the patient on top (these range from 70 to 85 cm in diameter). The distance between the layer on which the patient rests and the layer which rests on the therapy system couch is 18 to 30 cm to accommodate most breast sizes. The table is made from carbon-fiber to minimize thickness and radiation absorption. A soft, cushion lining is attached to the patient layer for comfort. |

Intended use

ClearVue Prone Breast Treatment Table, a breast radiation therapy patient support, is an accessory for medical linear accelerator radiation therapy systems. ClearVue is intended to be used to position and re-position patients for breast radiation therapy. ClearVue may be used with CT and MR scanners to acquire images for radiation therapy planning.

Comparison to the predicate device

| Characteristic | ClearVue | Bionix RT-6025 |
|---|---|---|
| Connection to accelerator patient table | Rests on table with high friction feet to prevent movement. An optional fixture locks to the table. | Locks to table |
| Prone position for breast treatment | Same | Same |
| Patient cushion | Cushioned body and head support | Massage-style face cushion supports the head with openings for air flow. |
| Contralateral breast protection | Same | Same |
| Comfortable foam support during treatment | Same | Same |
| Height | 7" to 12" | 9" |
| Weight | 28 pounds | 18 pounds |

Conclusion

The ClearVue is substantially equivalent to the Bionix RT-6025 Prone Breast System with respect to intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2009

Orbital Therapy, LLC
% Mr. Chas Burr
President
Chas Burr Q/R Services, Inc.
11 Mystic Avenue
WINCHESTER MA 01890

Re: K090349
Trade/Device Name: ClearVue Prone Breast Treatment Table
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 10, 2009
Received: February 11, 2009

Dear Mr. Burr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | (240) 276-0115 |
| 21 CFR 892.xxx | (Radiology) | (240) 276-0120 |
| Other | | (240) 276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K090349

Device Name: ClearVue Prone Breast Treatment Table

Indications for Use:

ClearVue, a breast radiation therapy patient support, is an accessory for medical linear accelerator radiation therapy systems. ClearVue is intended to be used to position and re-position patients for breast radiation therapy. ClearVue may be used with CT and MR scanners to acquire images for radiation therapy planning.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090349